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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/796,566	03/08/2004	Clark R. Baker JR.	TYHC:0069/FLE (P0426R)	1089

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EXAMINER

TOTH, KAREN E

ART UNIT	PAPER NUMBER
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3735

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	12/28/2006	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/796,566

Applicant(s)

BAKER, CLARK R.

Examiner

Karen E. Toth

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>7/22/05</u> . | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Chin (US Patent 6374129).

Regarding claim 1, Chin discloses a method of using a pulse oximeter to determine a heart rate comprising determining a first heart rate from a pulse oximetry signal using a first method (element 70); determining a second heart rate from a pulse oximetry signal using a second method (element 74); evaluating a reliability of the first heart rate by applying metrics to the first method; and using the first heart rate when it is reliable, and the second heart rate when it is not (column 8 line 58 to column 9 line 7).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chin in view of Leon (US Patent 5365934).

Chin discloses all the elements of the current invention, as described above, except for determining that the first heart rate is unreliable after a pulse is rejected.

Leon discloses a method of using multiple heart rate signals to determine an accurate heart rate where a first rate is considered unreliable after it is rejected, in favor of an alternate heart rate candidate (column 12, lines 46-52), in order to ensure that the most accurate heart rate is obtained. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the method of Chin and considered the first heart rate to be unreliable after its rejection, as taught by Leon, in order to ensure that the most accurate heart rate is obtained.

6. Claims 3 and 4 are rejected under 35 U.S.C. 103(a) as being obvious over Chin in view of Baker (US Patent Application Publication 2002/0137994).

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Regarding claim 3, Chin discloses all the elements of the current invention, as described above, except for one of the methods of determining a heart rate using an ensemble averaged waveform.

Baker teaches using pulse oximetry to obtain heart rate signals where, as part of determining the most accurate heart rate signal, the pulse period of a particular set of signals (that is, an ensemble), may be averaged (paragraph [0057]), in order to determine an accurate heart rate. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the method of Chin and chosen to use an ensemble averaged waveform, as taught by Baker, for one of the methods, such as the first one, since the technique is well known in the art for determining an accurate heart rate.

Regarding claim 4, Chin discloses all the elements of the current invention, as described above, except for determining the heart rate by determining a pulse period and converting it to a rate.

Baker teaches using pulse oximetry to obtain heart rate signals, where the signals are used to determine a pulse period (average period of the pleth), which is converted into a heart rate (pulse rate) (paragraph [0057]), in order to accurately monitor the patient. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the method of Chin and determined the heart rate from a pulse period, as taught by Baker, in order to accurately monitor the patient.

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7. Claims 5 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zahorian (US Patent 5524631) in view of Baker.

Regarding claim 5, Zahorian discloses a device that determines a heart rate comprising a first heart rate calculator for determining a first heart rate from a signal using a first method and a second heart rate calculator for determining a second heart rate from a second signal using a second method (column 3 line 66 to column 7 line 3; column 5, lines 46-48 and 53-55); an evaluator configured to determine the reliability of the first heart rate using metrics (column 8, lines 16-29); and a selector configured to use the first heart rate when it is deemed reliable and the second heart rate when it is not (column 8, lines 36-45). Zahorian does not disclose using a pulse oximeter to obtain the heart rate signals.

Baker teaches a device using a pulse oximeter when determining an accurate heart rate from a plurality of potential heart rate signals (paragraphs [0033]-[0036]), in order to accurately and non-invasively obtain heart rate signals. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the device of Zahorian and used pulse oximetry to obtain the heart rate signals, as taught by Baker, in order to accurately and non-invasively obtain the signals.

Regarding claim 7, Zahorian in view of Baker teaches all the elements of the current invention except for the first heart rate calculator using an ensemble averaged wave form and the second not. Baker further teaches using pulse oximetry to obtain heart rate signals where, as part of determining the most accurate heart rate signal, the pulse period of a particular set of signals (that is, an ensemble), may be averaged

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(paragraph [0057]), in order to determine an accurate heart rate. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the method of Zahorian in view of Baker and chosen to use an ensemble averaged waveform, as further taught by Baker, for one of the methods, such as the first one, since the technique is well known in the art for determining an accurate heart rate.

8. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Zahorian in view of Baker, as applied to claims 5 and 7 above, and further in view of Leon.

Zahorian in view of Baker discloses all the elements of the current invention, except for the selector determining that the first heart rate is unreliable when metrics indicate that a pulse is rejected.

Leon discloses using multiple heart rate signals to determine an accurate heart rate where a first rate is considered by a selector to be unreliable after it is rejected, in favor of an alternate heart rate candidate (column 12, lines 46-52), in order to ensure that the most accurate heart rate is obtained. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the device of Zahorian in view of Baker and considered the first heart rate to be unreliable after its rejection, as taught by Leon, in order to ensure that the most accurate heart rate is obtained.

Conclusion

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9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US Patent 6178343 to Bindzus, which discloses a similar system and method.


US Patent 6584336 to Ali, which discloses a similar system and method.

US Patent 5485847 to Baker, which discloses a similar system and method.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen E. Toth whose telephone number is 571-272-6824. The examiner can normally be reached on Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on 571-272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


CHARLES A. MARMOR II
SUPERVISORY PATENT EXAMINER
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